Complete Summary

GUIDELINE TITLE

American Society of Clinical Oncology guideline: recommendations for venous thromboembolism prophylaxis and treatment in patients with cancer.

BIBLIOGRAPHIC SOURCE(S)

Lyman GH, Khorana AA, Falanga A, Clarke-Pearson D, Flowers C, Jahanzeb M, Kakkar A, Kuderer NM, Levine MN, Liebman H, Mendelson D, Raskob G, Somerfield MR, Thodiyil P, Trent D, Francis CW. American Society of Clinical Oncology guideline: recommendations for venous thromboembolism prophylaxis and treatment in patients with cancer. J Clin Oncol 2007 Dec 1;25(34):5490-505. [146 references] PubMed

GUIDELINE STATUS

This is the current release of the guideline.

** REGULATORY ALERT **

FDA WARNING/REGULATORY ALERT

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- February 28, 2008, Heparin Sodium Injection: The U.S. Food and Drug Administration (FDA) informed the public that Baxter Healthcare Corporation has voluntarily recalled all of their multi-dose and single-use vials of heparin sodium for injection and their heparin lock flush solutions. Alternate heparin manufacturers are expected to be able to increase heparin production sufficiently to supply the U.S. market. There have been reports of serious adverse events including allergic or hypersensitivity-type reactions, with symptoms of oral swelling, nausea, vomiting, sweating, shortness of breath, and cases of severe hypotension.
- August 16, 2007, Coumadin (Warfarin): Updates to the labeling for Coumadin to include pharmacogenomics information to explain that people's genetic makeup may influence how they respond to the drug.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Cancer
Venous thromboembolism (VTE)

GUIDELINE CATEGORY

Prevention
Treatment

CLINICAL SPECIALTY

Oncology
Surgery

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To develop guideline recommendations for the use of anticoagulation in the prevention and treatment of venous thromboembolism (VTE) in patients with cancer

Specifically, to address the following questions:

1. Should hospitalized patients with cancer receive anticoagulation for VTE prophylaxis?
2. Should ambulatory patients with cancer receive anticoagulation for VTE prophylaxis during systemic chemotherapy?
3. Should patients with cancer undergoing surgery receive perioperative VTE prophylaxis?
4. What is the best method for treatment of patients with cancer with established VTE to prevent recurrence?
5. Should patients with cancer receive anticoagulants in the absence of established VTE to improve survival?

TARGET POPULATION

Patients with cancer, including:

- Hospitalized patients
- Patients without venous thromboembolism (VTE) receiving chemotherapy on an ambulatory basis
- Patients undergoing surgery (perioperative and postoperative periods)
- Patients with recent prior VTE
- Patients without an established VTE

INTERVENTIONS AND PRACTICES CONSIDERED

Prevention/Treatment

1. Anticoagulation
    - Unfractionated heparin (UFH)
    - Low molecular weight heparin (LMWH)
    - Fondaparinux
    - Warfarin
    - Vitamin K antagonists
2. Mechanical prophylaxis
    - Graduated compression stockings
    - Intermittent pneumatic compression (IPC)
    - Mechanical foot pumps

MAJOR OUTCOMES CONSIDERED

- Survival
- Prevention of venous thromboembolism (VTE)
- Complications of treatment

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Literature Search Strategy

An exhaustive systematic literature review was performed of randomized clinical trials (RCTs) examining the efficacy and safety of anticoagulation therapy in patients with cancer regarding survival, bleeding complications, and the prevention of venous thromboembolism (VTE). The comprehensive search included the following electronic databases through the end of 2006: MEDLINE,

EMBASE, Cancerlit, Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, Database of Abstracts of Reviews of Effect, and National Guideline Clearing House. Conference proceedings were searched from 2003 to 2006 (American Society of Clinical Oncology [ASCO], American Society of Hematology, International Society of Thrombosis and Hemostasis). References from included articles, relevant excluded reports, and guidelines were searched by hand. In addition, the VTE Panel and other experts from North America and Europe were asked to review identified articles to ensure completeness and provide unpublished results. The literature search had no language restrictions. Subject headings and keywords used in the search process included four major categories, including medical subject headings and text words: venous thromboembolism; anticoagulation including vitamin K antagonists, unfractionated heparin (UFH), and low molecular weight heparin (LMWH); and all malignancies including solid tumors and hematologic malignancies. For RCTs, the recommended search strategy from the Cochrane Collaboration was used. These three major search categories were combined by the Boolean "AND." The terms utilized within these major search categories were combined by the Boolean "OR."

Inclusion and Exclusion Criteria

Included studies had to be RCTs of adult patients with cancer randomly assigned to anticoagulation drug therapy or an appropriate control group. Anticoagulation had to be with LMWH, UFH, or an oral vitamin K antagonist. Studies were only included if they had VTE or mortality as a priori planned primary or secondary outcomes and described a method of regular patient follow-up to ensure a consistent and identical identification of the outcomes in both study arms. VTE had to be confirmed objectively.

Studies were excluded if they were nonrandomized reports, post hoc subgroup analyses, or if they included only patients who did not have cancer. Given the substantial clinical differences, studies of thrombosis prophylaxis related to indwelling catheters were not included in this analysis. Among duplicate publications only the most recent or the most complete report was included.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Data Extraction

Two reviewers extracted the data independently on basic study design, patient characteristics, study outcomes, and measures of study quality. Any discrepancies between reviewers were resolved by consensus. Data for analysis were abstracted systematically from the published reports and included authors and citation; category, general type, and stage of malignancy and other demographic patient characteristics; drugs, doses, and schedule of anticoagulation therapy and concomitant interventions; study design (e.g., the type of control group [placebo v nonplacebo], appropriate description of randomization, blinding, concealment of therapy, description of patient withdrawals or dropouts, power calculations, and intention to treat analysis); and number of patients initially randomly assigned, the number of patients assessable, and the cumulative proportion experiencing specific outcomes.

Study Quality

Overall study quality was evaluated by the method of Moher et al., 1995*. This scale represents a validated instrument for assessing the quality of randomized clinical trials (RCTs). It evaluates study quality based on appropriate methods of randomization, appropriate description of blinding and treatment concealment, and appropriate description of study withdrawals or dropouts. The possible scoring range is from 0 to 5, with poor quality represented by a score of 2 or less.

*Moher D, Jadad AR, Nichol G, et al: Assessing the quality of randomized controlled trials: An annotated bibliography of scales and checklists. Control Clin Trials 16:62-73, 1995

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The American Society of Clinical Oncology (ASCO) Health Services Committee (HSC) convened an Expert Panel consisting of experts in clinical medicine and research relevant to venous thromboembolism (VTE) in patients with cancer including medical and surgical oncology. Academic and community practitioners, an oncology fellow, and a patient representative were also part of the Panel.

The entire Panel met twice; additional work on the guideline was completed through a steering group. The purposes of the Panel meetings were to refine the questions addressed by the guidelines and to make writing assignments for the respective guideline sections. All members of the Panel participated in the preparation of the draft guideline document, which was then disseminated for review.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Guideline developers reviewed published cost analyses.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

All members of the Expert Panel participated in the preparation of the draft guideline document, which was then disseminated for review by the entire Panel. Feedback from external reviewers was also solicited. The content of the guidelines and the manuscript were reviewed and approved by the Health Services Committee (HSC) and by the American Society of Clinical Oncology (ASCO) Board of Directors before dissemination.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Should Hospitalized Patients with Cancer Receive Anticoagulation for Venous Thromboembolism (VTE) Prophylaxis?

Recommendation

Hospitalized patients with cancer should be considered candidates for VTE prophylaxis with anticoagulants in the absence of bleeding or other contraindications to anticoagulation.

Should Ambulatory Patients with Cancer Receive Anticoagulation for VTE Prophylaxis During Systemic Chemotherapy?

Recommendations

1. Routine prophylaxis with an antithrombotic agent is not recommended.
2. Patients receiving thalidomide or lenalidomide with chemotherapy or dexamethasone are at high risk for thrombosis and warrant prophylaxis. Until such time as data are available from randomized clinical trials (RCTs), low-molecular-weight-heparin (LMWH) or adjusted-dose warfarin (international normalized ratio [INR] ~1.5) is recommended in myeloma patients receiving thalidomide plus chemotherapy or dexamethasone. *This recommendation is based on extrapolation from studies of postoperative prophylaxis in orthopedic surgery and a trial of adjusted-dose warfarin in breast cancer*.
3. RCTs evaluating antithrombotic agents are needed in patients with multiple myeloma receiving thalidomide or lenalidomide plus chemotherapy and/or dexamethasone.

4. Research identifying better markers of ambulatory patients with cancer most likely to develop VTE is urgently needed.

Should Patients with Cancer Undergoing Surgery Receive Perioperative VTE Prophylaxis?

Recommendations

1. All patients undergoing major surgical intervention for malignant disease should be considered for thromboprophylaxis.
2. Patients undergoing laparotomy, laparoscopy, or thoracotomy lasting greater than 30 minutes should receive pharmacologic thromboprophylaxis with either low-dose unfractionated heparin (UFH) or LMWH unless contraindicated because of a high risk of bleeding or active bleeding.
3. Prophylaxis should be commenced preoperatively, or as early as possible in the postoperative period.
4. Mechanical methods may be added to pharmacologic methods, but should not be used as monotherapy for VTE prevention unless pharmacologic methods are contraindicated because of active bleeding.
5. A combined regimen of pharmacologic and mechanical prophylaxis may improve efficacy, especially in the highest-risk patients.
6. Prophylaxis should be continued for at least 7 to 10 days postoperatively. Prolonged prophylaxis for up to 4 weeks may be considered in patients undergoing major abdominal or pelvic surgery for cancer with high-risk features such as residual malignant disease after operation, obese patients, and those with a previous history of VTE.

What is the Best Treatment for Patients with Cancer with Established VTE to prevent Recurrent VTE?

Recommendations

1. LMWH is the preferred approach for the initial 5 to 10 days of anticoagulant treatment of the cancer patient with established VTE.
2. LMWH given for at least 6 months is also the preferred approach for long-term anticoagulant therapy. Vitamin K antagonists with a targeted INR of 2 to 3 are acceptable for long-term therapy when LMWH is not available.
3. After 6 months, indefinite anticoagulant therapy should be considered for selected patients with active cancer, such as those with metastatic disease and those receiving chemotherapy. This recommendation is based on Panel consensus in the absence of clinical trials data.
4. The insertion of a vena cava filter is only indicated for patients with contraindications to anticoagulant therapy and in those with recurrent VTE despite adequate long-term therapy with LMWH.
5. For patients with central nervous system (CNS) malignancies, anticoagulation is recommended for established VTE as described for other patients with cancer. Careful monitoring is necessary to limit the risk of hemorrhagic complications. Anticoagulation should be avoided in the presence of active intracranial bleeding, recent surgery, preexisting bleeding diathesis such as thrombocytopenia (platelet count <50,000/microliter) or coagulopathy.
6. For elderly patients, anticoagulation is recommended for established VTE as described for other patients with cancer. Careful monitoring and dose

adjustment is necessary to avoid excessive anticoagulation and further increase in the risk of bleeding.

Should Patients with Cancer Receive Anticoagulants in the Absence of Established VTE to Improve Survival?

Recommendations

1. Anticoagulants are not recommended to improve survival in patients with cancer without VTE.
2. Patients with cancer should be encouraged to participate in clinical trials designed to evaluate anticoagulant therapy as an adjunct to standard anticancer therapies.

CLINICAL ALGORITHM(S)

An algorithm entitled: American Society of Clinical Oncology (ASCO) Prophylaxis Algorithm for Venous Thromboembolism: 2007 is provided as a companion document (see "Availability of Companion Documents" field in this summary).

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations were based primarily on comprehensive review of published reports. In cases where the data did not appear conclusive, recommendations were based on the consensus opinion of the group. The type of evidence supporting each recommendation is summarized in Table 5 of the original guideline document.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate venous thromboembolism prophylaxis and treatment in patients with cancer

POTENTIAL HARMS

Hemorrhagic complications of anticoagulation

Caution is advised in the use of anticoagulation in the following high-risk patient groups:

- Recent surgery and history of venous thromboembolism
- Recent intracranial surgery
- High risk of falls
- Preexisting bleeding diathesis
- Preexisting coagulopathy
- Poor compliance with medical therapy

CONTRAINDICATIONS

CONTRAINDICATIONS

Anticoagulant therapy is absolutely contraindicated in patients with active intracranial bleeding.

Relative contraindications for anticoagulation:

- Active, uncontrollable bleeding
- Active cerebrovascular hemorrhage
- Dissecting or cerebral aneurysm
- Bacterial endocarditis
- Pericarditis, active peptic or other gastrointestinal (GI) ulceration
- Severe, uncontrolled or malignant hypertension
- Severe head trauma
- Pregnancy (warfarin)
- Heparin-induced thrombocytopenia (heparin, low-molecular-weight-heparin [LMWH])
- Epidural catheter placement

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- It is important to emphasize that guidelines cannot always account for individual variation among patients. They are not intended to supplant physician judgment regarding particular patients or special clinical situations, and cannot be considered inclusive of all proper methods of care or exclusive of other treatments reasonably directed at obtaining the same result. Accordingly, the American Society of Clinical Oncology (ASCO) considers adherence to these guidelines to be voluntary, with the ultimate determination regarding their application to be made by the physician in light of each patient's circumstances.
- In addition, these guidelines describe the use of procedures and therapies in clinical practice; they cannot be assumed to apply to the use of these interventions performed in the context of clinical trials, given that clinical studies are designed to evaluate or validate innovative approaches in a disease for which improved management is needed. Because guideline development involves a review and synthesis of the literature, a practice guideline also serves to identify important questions and settings for further research.

Limitations of the Evidence

Patients with cancer represent a high-risk population for venous thromboembolism (VTE) and associated complications including early mortality. The effective and safe prevention of VTE in this population is a laudable goal but remains a challenge in terms of both treatment-associated toxicities and variable evidence from clinical trials, in addition to meta-analyses of such trials. The guideline presented here offers explicit recommendations for the use of

anticoagulation and other measures for the prevention of VTE in hospitalized patients with cancer, those receiving cancer chemotherapy on an ambulatory basis, patients with cancer in the perioperative and postoperative period, those with recent prior VTE, and finally, for patients with cancer without an established VTE as a possible adjunct to cancer therapy. Nevertheless, the available data addressing these and related issues are limited. There remains a considerable need for additional research, particularly in the form of large, well-designed, randomized, controlled clinical trials. Systematic reviews and meta-analyses of clinical trials serve a useful purpose in systematically searching for the totality of evidence and, when appropriate, combining the results of smaller and often inconclusive trials. Nevertheless, the quality and validity of meta-analyses are only as valid as those of the individual clinical trials included.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Chart Documentation/Checklists/Forms
Clinical Algorithm
Patient Resources
Personal Digital Assistant (PDA) Downloads
Quick Reference Guides/Physician Guides
Slide Presentation

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Lyman GH, Khorana AA, Falanga A, Clarke-Pearson D, Flowers C, Jahanzeb M, Kakkar A, Kuderer NM, Levine MN, Liebman H, Mendelson D, Raskob G,

Somerfield MR, Thodiyil P, Trent D, Francis CW. American Society of Clinical Oncology guideline: recommendations for venous thromboembolism prophylaxis and treatment in patients with cancer. J Clin Oncol 2007 Dec 1;25(34):5490-505. [146 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2007 Dec

GUIDELINE DEVELOPER(S)

American Society of Clinical Oncology - Medical Specialty Society

SOURCE(S) OF FUNDING

American Society of Clinical Oncology

GUIDELINE COMMITTEE

American Society of Clinical Oncology (ASCO) Venous Thromboembolism Expert Panel

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

All members of the Expert Panel complied with American Society of Clinical Oncology (ASCO) policy on conflicts of interest, which requires disclosure of any financial or other interest that might be construed as constituting an actual, potential, or apparent conflict. Members of the Expert Panel completed ASCO's disclosure form and were asked to reveal ties to companies developing products that might be affected by promulgation of the guidelines. Information was requested regarding employment, consultancies, stock ownership, honoraria, research funding, expert testimony, and membership on company advisory committees. The Panel made decisions on a case-by-case basis as to whether an individual's role should be limited as a result of a conflict. No limiting conflicts were identified.

Although all authors completed the disclosure declaration, the following author(s) indicated a financial or other interest that is relevant to the subject matter under consideration in this article. Certain relationships marked with a "U" are those for which no compensation was received; those relationships marked with a "C" were compensated. For a detailed description of the disclosure categories, or for more information about ASCO's conflict of interest policy, please refer to the Author Disclosure Declaration and the Disclosures of Potential Conflicts of Interest section in Information for Contributors in the original journal of publication.

Employment or Leadership Position: None **Consultant or Advisory Role**: Ajay Kakkar, Sanofi-aventis (C), Pfizer (C), Eiasi Pharmaceuticals (C); Howard Liebman, laxoSmithKline (C), Pfizer (C), Bristol-Myers Squibb (C); Gary Raskob, Sanofi-aventis (C), Bayer (C), Bristol-Myers Squibb (C), Boehringer-Ingelheim (C), Darichi (C), Takeda (C); Charles W. Francis, Eisai Pharmaceuticals (C) **Stock Ownership**: None **Honoraria**: Alok A. Khorana, Sanofi-aventis, Eisai Pharmaceuticals; Ajay Kakkar, Sanofi-aventis, Pfizer, Eiasi Pharmaceuticals; Howard Liebman, GlaxoSmithKline, Pfizer, Pharmion; Gary Raskob, Sanofi-aventis, Bayer, Boehringer-Ingelheim; Charles W. Francis, Eisai Pharmaceuticals **Research Funding**: Ajay Kakkar, Sanofi-aventis; Mark N. Levine, Pfizer; Howard Liebman, Bristol-Myers Squibb, Pharmion, Pfizer **Expert Testimony**: Daniel Clarke-Pearson (C); Mark N. Levine (C); Gary Raskob (C) **Other Remuneration**: None

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American Society of Clinical Oncology (ASCO) Web site.

Print copies: Available from American Society of Clinical Oncology, Cancer Policy and Clinical Affairs, 1900 Duke Street, Suite 200, Alexandria, VA 22314; E-mail: guidelines@asco.org.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- VTE prophylaxis orders and flow sheet. 1 p. Available in Portable Document Format (PDF) from the American Society of Clinical Oncology (ASCO) Web site.
- ASCO prophylaxis algorithm for venous thromboembolism: 2007 and ASCO treatment algorithm for recurrent venous thromboembolism: 2007. 2 p. Available in Portable Document Format (PDF) from the American Society of Clinical Oncology (ASCO) Web site.
- Recommendations for venous thromboembolism prophylaxis and treatment in patients with cancer. Slide set. 2007. 23 p. Electronic copies: Available in Portable Document Format (PDF) and PowerPoint from the American Society of Clinical Oncology (ASCO) Web site.
- VTE prophylaxis guideline summary. 2007. 4 p. Electronic copies: Available from the ASCO Web site.

Guidelines are available for Personal Digital Assistant (PDA) download from the ASCO Web site.

PATIENT RESOURCES

The following is available:

- ASCO patient guide: preventing and treating blood clots. 2007. 3 p. Available from the Cancer.Net Web site.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

This NGC summary was completed by ECRI Institute on February 19, 2008. The information was verified by the guideline developer on February 20, 2008. This summary was updated by ECRI Institute on March 14, 2008 following the updated FDA advisory on heparin sodium injection.

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